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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,537	06/21/2001	Myron Spector	1194-176	2633

6449 7590 10/02/2002

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,537

Applicant(s)

Spector et al.

Examiner

Stephen Kucher

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/2/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-21 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-17 & 19-21 is/are rejected.
- ☒ Claim(s) 18 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 6
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Claims 1-6, 9, 11-17, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Geislich et al. (U.S. Patent No. 6,221,109 B1; "'109") in light of Geislich et al. (U.S. Patent No. 5,573,771; "'771").

The '109 patent discloses a single sheet of collagen wrapped around the spinal cord to form a tube (see Figure 1). This tube may be made of Biogide (column 2, lines 4-9), thereby meeting the limitations of the instant claims (see also page 3 of the instant specification for more inherent features of Biogide). The Biogide tube may be filled with Bio-Oss Collagen (column 2, lines 49-52), the inherent features of which are disclosed in the '771 patent, column 2, lines 23-52. Bio-Oss Collagen may be impregnated with morphogenic and angiogenic factors ('771 patent, column 3, lines 56-58) which would act as a nerve growth stimulant (e.g. bone morphogenic factors or proteins (BMPs) are known in the art to be neurotrophic). Note that the Biogide sheet may be double or triple wrapped around the spinal cord, forming a tube filled with

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longitudinal collagen fibers from the multiple wrappings (see Figures 3-5 of the "109 patent), in addition to fibers being formed in the Bio-Oss Collagen filling.

4. Claims 1-2, 5-7, 9-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Shizmu for reasons of record and the following.

Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive because Applicant argues that Shizmu teaches a sidewall with three layers with the central layer being made of a non-collagen material (page 4 of Amendment A). However, Shizmu also discloses a pure collagen sidewall without the use of any non-collagen materials (column 6, line 48 to column 7, line 50).

5. Claims 1, 5, and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shizmu as applied above in view of Tongue et al. for reasons of record and the following.

Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive because Applicant argues that Shizmu teaches a sidewall with three layers with the central layer being made of a non-collagen material (page 4 of Amendment A). However, Shizmu also discloses a pure collagen sidewall without the use of any non-collagen materials (column 6, line 48 to column 7, line 50).

6. Claims 1 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shizmu as applied above in view of Geistlich et al. (US 5,837,278) for reasons of record and the following.

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Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive because Applicant argues that Shizmu teaches a sidewall with three layers with the central layer being made of a non-collagen material (page 4 of Amendment A). However, Shizmu also discloses a pure collagen sidewall without the use of any non-collagen materials (column 6, line 48 to column 7, line 50).

7. Claims 1, 15-17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shizmu as applied above in view of Stensaas et al. for reasons of record and the following.

Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive because Applicant argues that Shizmu teaches a sidewall with three layers with the central layer being made of a non-collagen material (page 4 of Amendment A). However, Shizmu also discloses a pure collagen sidewall without the use of any non-collagen materials (column 6, line 48 to column 7, line 50).

8. Claim 18 is objected to as being dependent on a rejected claim but would be allowable if written in independent form incorporating the limitations of the base claim.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached

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on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Stephen Gucker

October 1, 2002

Gary D. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
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